

Respiratory Syncytial Virus (RSV) Recommendations for Adults, Infants, and Young Children November 2, 2023

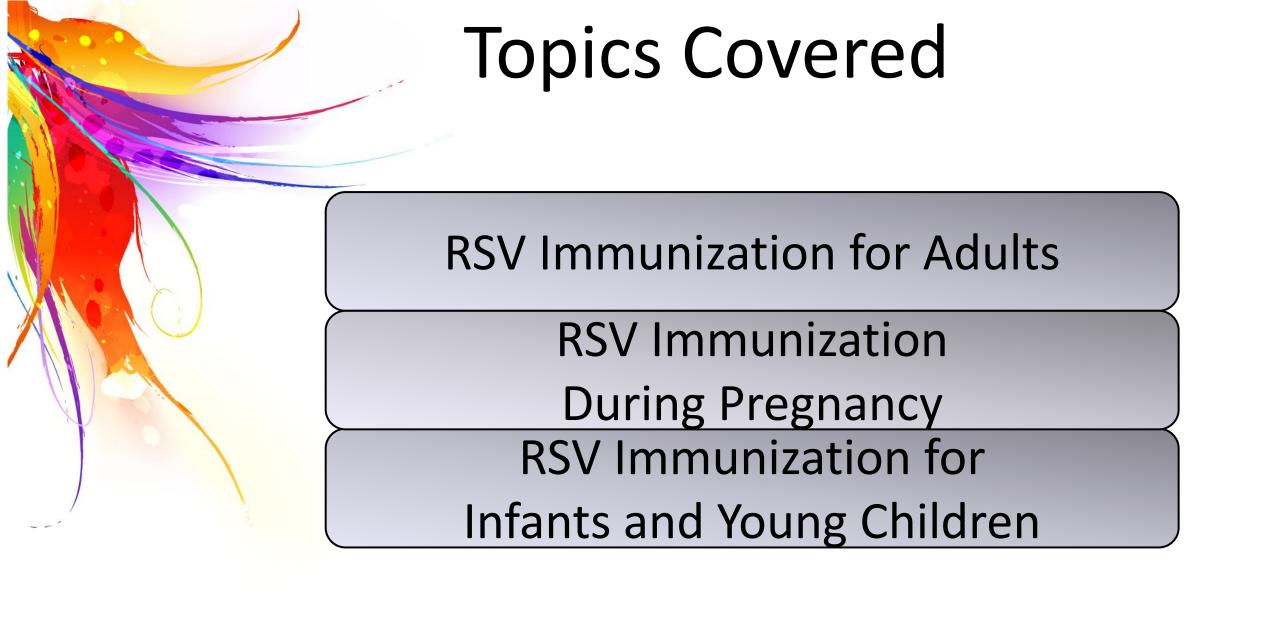
# Housekeeping

## **How to Ask Questions**

- Click on the icon found at the bottom part of your screen
- A box will open where you can type in questions, comments, indicate sound problems, etc.
- Use this throughout the webinar to ask questions

## **Slides & Recording**

 This webinar is being recorded and a link as well as slides will be emailed out through our listserv as well as posted on the MDHHS Seasonal Respiratory Viruses website at: <a href="www.michigan.gov/mdhhs/keep-mi-healthy/chronicdiseases/seasonal-respiratory-viruses">www.michigan.gov/mdhhs/keep-mi-healthy/chronicdiseases/seasonal-respiratory-viruses</a>



## New Immunizations to Protect Against Severe RSV

	Who Does It Protect?	Type of Product	Is It for Everyone in Group?
	Adults 60 and over	RSV vaccine	Talk to your doctor first
	Babies	RSV antibody given to baby	All infants entering or born during RSV season. Small group of older babies for second season.
WE THE PARTY OF TH	Babies	OR  RSV vaccine given during pregnancy	Can get if you are 32–36 weeks pregnant during September–January

www.cdc.gov/rsv





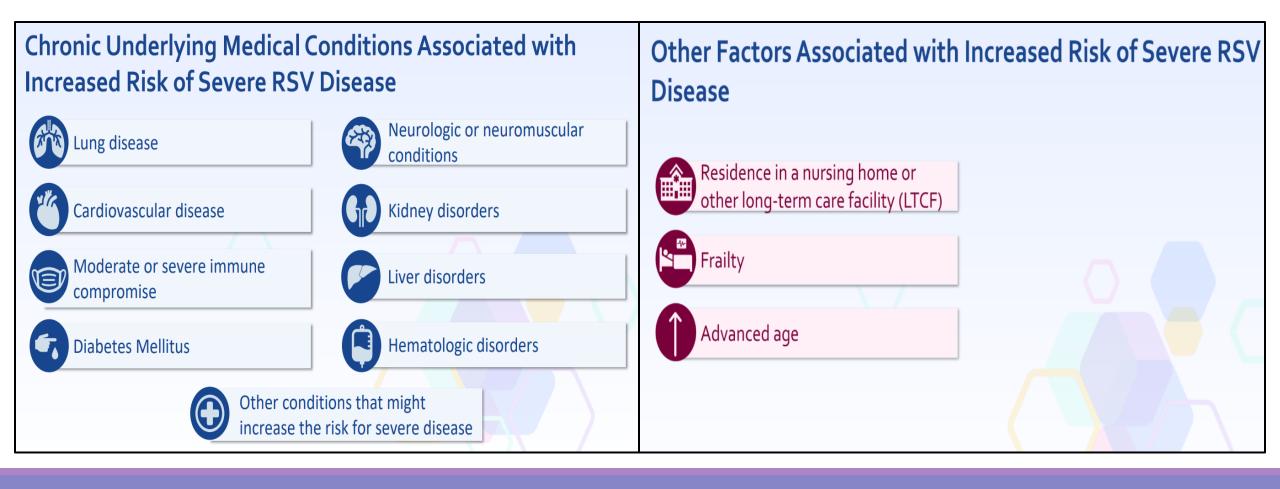
# **RSV Immunization for Adults**

## **RSV Immunization for Adults**

- RSV is a cause of severe respiratory illness in older adults
- Each season, RSV causes substantial morbidity and mortality in older adults, including lower respiratory tract disease (LRTD), hospitalization, and death
- On July 21, 2023, the CDC published a Morbidity and Mortality Weekly Report (MMWR) with recommendations for the new adult RSV vaccines Arexvy (GSK), and Abrysvo (Pfizer) titled: <u>Use of Respiratory Syncytial Virus Vaccines in Older Adults: Recommendations of the Advisory Committee on Immunization Practices — United States, 2023</u>
- Recommendation: Adults aged 60 years and older may receive a single dose of either RSV vaccine, using shared clinical decision-making with their healthcare provider
  - Shared clinical decision-making is intended to allow flexibility for providers and patients to consider individual risk for RSV disease, while considering patient preferences

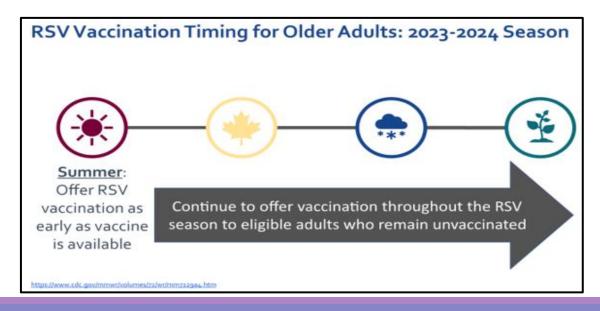
## RSV Immunization for Adults Cont.

 Persons aged 60 years and older who are at highest risk for severe RSV disease and who might be most likely to benefit from vaccination include:



## **RSV Immunization for Adults**

- There are two vaccines for use in the prevention of RSV:
  - Abrysvo (Pfizer) is a 1-dose 0.5mL recombinant stabilized prefusion F protein vaccine administered intramuscularly (IM) and requires reconstitution
    - Approved for use in people ages 60 years and older AND pregnant people
  - Arexvy (GSK) is a 1-dose 0.5mL adjuvanted recombinant stabilized prefusion F protein vaccine administered intramuscularly (IM) and requires reconstitution
    - Approved for use ONLY in people ages 60 years and older
  - o There is no preferential recommendation for either vaccine; give whichever vaccine is available
- For the 2023–24 season, clinicians should offer RSV vaccination to adults aged 60 years and older using shared clinical decision-making as early as vaccine supply becomes available and should continue to offer vaccination to eligible adults who remain unvaccinated



# Abrysvo (Pfizer): Storage and Handling

### BEFORE Reconstitution

- Store refrigerated between 2°C and 8°C (36°F and 46°F)
- Do NOT freeze
- AFTER Reconstitution administer immediately - If unable to administer:
  - Store at room temperature 15°C to 30°C (59°F to 86°F)
  - Do NOT refrigerate
  - Do NOT freeze
  - Use within 4 hours (beyond use time)

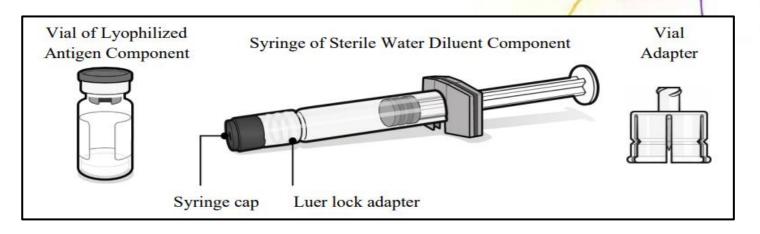


RSVpreF (Abrysvo, Pfizer, Inc.)

Abrysvo (Pfizer): Preparation and Administration

- Supplied in a kit that includes:
  - Vial of Lyophilized Antigen Component (a sterile white powder)
  - Prefilled syringe containing Sterile Water Diluent Component
  - Vial Adapter
  - Syringe cap with Luer lock adapter
- To form ABRYSVO, reconstitute the Lyophilized Antigen Component with the accompanying Sterile Water Diluent
- Gently swirl until powder is completely dissolved, do not shake vial
- A single dose after
- reconstitution is 0.5 mL





# Arexvy (GSK): Storage and Handling

### BEFORE Reconstitution

- Store refrigerated between 2°C and 8°C (36°F and 46°F)
- Do NOT freeze
- Protect from light
- AFTER Reconstitution administer immediately - If unable to administer:
  - Store refrigerated between 2°C and 8°C (36°F and 46°F) OR at room temperature up to 25°C (77°F)
  - Do NOT freeze
  - Protect from light
  - Use within 4 hours (beyond use time)



RSVPreF3 (Arexvy, GSK)

# Arexvy (GSK): Preparation and Administration

- Supplied in 2 vials that must be combined prior to administration
- Reconstitute the lyophilized antigen component (a sterile white powder) with the accompanying adjuvant suspension component (an opalescent, colorless to pale brownish sterile liquid)
- Use only the supplied adjuvant suspension component for reconstitution
- Gently swirl the vial until powder is completely dissolved. Do not shake vigorously
- Reconstituted vaccine should be an opalescent, colorless to pale brownish liquid
- Inspect visually for particulate matter and discoloration prior to administration
  - If either of these conditions exists, the vaccine should not be administered
- Administer Intramuscular (IM)
  - o Dose 0.5 mL



- Per General Best Practice Guidelines for Immunization:
  - Coadministration with all other adult vaccines is acceptable
  - If vaccines are NOT administered the same day, there is no required interval between vaccines
- Considerations for coadministration for RSV vaccine in older adults:
  - Whether the patient is up to date with currently recommended vaccines
  - Feasibility of the patient returning for additional vaccine doses
  - Risk for acquiring vaccine-preventable disease
  - Vaccine reactogenicity profiles
  - Patient preferences



# RSV Immunization for Pregnant People

- August 21, 2023, <u>FDA</u> approved Abrysvo for use in pregnant people who are 32 through 36 weeks gestation to prevent RSV
- September 22, 2023, ACIP met and voted to recommend
   Abrysvo for use in pregnant people who are 32 through 36
   weeks gestation, using seasonal administration to prevent RSV
   (VFC resolution was also passed)
  - CDC endorsed this recommendation on the same day
- Most infants will likely only need protection from either the maternal RSV vaccine or infant immunization, but not both
- MMWR was published on October 6, 2023

# Clinical Guidance for Use of Abrysvo

- Pregnant people should get a single dose of Pfizer's bivalent RSVpreF vaccine (Abrysvo) during weeks 32 through 36 of pregnancy during September through January (seasonality of RSV season can vary)
- Vaccine can be administered with other recommended vaccines, such as tetanus, diphtheria, and pertussis (Tdap), influenza, and COVID-19 vaccines, without regard to timing, including simultaneous vaccination at different anatomic sites on the same day

# Clinical Guidance for Use of Abrysvo Cont.

- Either Abrysvo at 32 through 36 weeks gestation **OR** nirsevimab administration is recommended, but administration of both products is not needed for most infants
  - Providers who care for pregnant persons should discuss the advantages and disadvantages of both Abrysvo and nirsevimab and consider patient preferences when determining whether to vaccinate the pregnant person or to rely on administration of nirsevimab to the infant. A list of advantages and disadvantages is outlined in the MMWR
- Mothers of most infants born outside of RSV season (i.e., during April– September) will not have been vaccinated; therefore, nirsevimab is recommended for these infants at the onset of the RSV season if they are less than 8 months old

# Advantages and Disadvantages of Abrysvo and Nirsevimab Administration

Both products are safe and effective in preventing RSV lower respiratory infection in infants

## Maternal RSVpreF Vaccine

- Advantages:
  - Provides protection immediately after birth
  - Might be more resistant to potential mutations in F protein
- Disadvantages:
  - Protection potentially reduced if fewer antibodies are produced or are transferred from pregnant person to baby (e.g., pregnant person is immunocompromised, or infant born soon after vaccination
  - Potential risk for preterm birth and hypertensive disorders of pregnancy

## Infant Nirsevimab Administration

- Advantages:
  - Studies of antibody levels suggest that protection might wane more slowly than protection from the maternal RSV vaccine
  - Assures direct receipt of antibodies rather than relying on transplacental transfer
  - No risk for adverse pregnancy outcomes
- Disadvantages:
  - Potentially limited availability during 2023-24
     RSV season
  - Requires infant injection

# Clinical Guidance for Use of Abrysvo and Nirsevimab

- Nirsevimab may be considered for infants born to vaccinated mothers in rare circumstances. These situations include but are not limited to:
  - Infants born to mothers who might not have mounted an adequate immune response to vaccination (e.g., persons with immunocompromising conditions) or who have conditions associated with reduced transplacental antibody transfer (e.g., persons living with HIV infection)
  - Infants who might have experienced loss of maternal antibodies such as those who have undergone cardiopulmonary bypass or extracorporeal membrane oxygenation
  - Infants with substantially increased risk for severe RSV disease (e.g., hemodynamically significant congenital heart disease, or intensive care admission requiring oxygen at hospital discharge)



## **New Interim Recommendations**

- Providers should encourage pregnant people to receive RSVpreF vaccine (Abrysvo, Pfizer) during 32 weeks' gestation through 36 weeks gestation to prevent RSV-associated lower respiratory tract disease in infants.
  - Only the Pfizer RSVpreF vaccine (Abrysvo) is approved and recommended for use in pregnant people. The GSK RSVpreF3 vaccine (Arexvy) should **not** be used in pregnant people

# Are Additional Doses of Abrysvo Recommended?

- Pfizer maternal RSV vaccine is recommended as a one-time dose at this time
- Currently, no data are available on either the efficacy of the first lifetime dose to protect infants born after subsequent pregnancies or the safety of additional doses given in subsequent pregnancies
- Additional data are needed to determine whether additional seasonal doses in subsequent pregnancies would be indicated
- ACIP might update recommendations in the future, as data become available

# Abrysvo (Pfizer): Storage and Handling

### BEFORE Reconstitution

- Store refrigerated between 2°C and 8°C (36°F and 46°F)
- Do NOT freeze
- AFTER Reconstitution administer immediately - If unable to administer:
  - Store at room temperature 15°C to 30°C (59°F to 86°F)
  - Do NOT refrigerate
  - Do NOT freeze
  - Use within 4 hours (beyond use time)

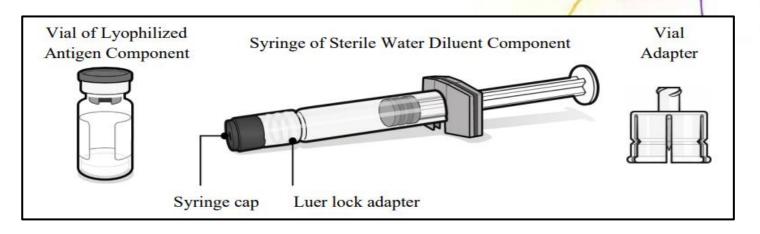


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- reconstitution is 0.5 mL





#### **VACCINE INFORMATION STATEMENT**

## RSV (Respiratory Syncytial Virus) Vaccine: What You Need to Know

Many vaccine information statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

#### 1. Why get vaccinated?

RSV vaccine can prevent lower respiratory tract disease caused by respiratory syncytial virus (RSV). RSV is a common respiratory virus that usually causes mild, cold-like symptoms.

RSV can cause illness in people of all ages but may be especially serious for infants and older adults.

- Infants up to 12 months of age (especially those 6 months and younger) and children who were born prematurely, or who have chronic lung or heart disease or a weakened immune system, are at increased risk of severe RSV disease.
- Adults at highest risk for severe RSV disease include older adults, adults with chronic medical conditions such as heart or lung disease, weakened immune systems, or certain other underlying medical conditions, or who live in nursing homes or long-term care facilities.

RSV spreads through direct contact with the virus, such as droplets from another person's cough or sneeze contacting your eyes, nose, or mouth. It can also be spread by touching a surface that has the virus on it, like a doorknob, and then touching your face before washing your hands.

Symptoms of RSV infection may include runny nose, decrease in appetite, coughing, sneezing, fever, or wheezing. In very young infants, symptoms of RSV may also include irritability (fussiness), decreased activity, or apnea (pauses in breathing for more than 10 seconds).

Most people recover in a week or two, but RSV can be serious, resulting in shortness of breath and low oxygen levels. RSV can cause bronchiolitis (inflammation of the small airways in the lung) and pneumonia (infection of the lungs). RSV can sometimes lead to worsening of other medical conditions such as asthma, chronic obstructive

pulmonary disease (a chronic disease of the lungs that makes it hard to breathe), or congestive heart failure (when the heart can't pump enough blood and oxygen throughout the body).

Older adults and infants who get very sick from RSV may need to be hospitalized. Some may even die.

#### 2. RSV vaccine

CDC recommends adults 60 years of age and older have the option to receive a single dose of RSV vaccine, based on discussions between the patient and their health care provider.

There are two options for protection of infants against RSV: maternal vaccine for the pregnant person and preventive antibodies given to the baby. Only one of these options is needed for most babies to be protected. CDC recommends a single dose of RSV vaccine for pregnant people from week 32 through week 36 of pregnancy for the prevention of RSV disease in infants under 6 months of age. This vaccine is recommended to be given from September through January for most of the United States. However, in some locations (the territories, Hawaii, Alaska, and parts of Florida), the timing of vaccination may vary as RSV circulating in these locations differs from the timing of the RSV season in the rest of the U.S.

RSV vaccine may be given at the same time as other vaccines.



#### 3. Talk with your health care provider

Tell your vaccination provider if the person getting the vaccine:

 Has had an allergic reaction after a previous dose of RSV vaccine, or has any severe, life-threatening allergies

In some cases, your health care provider may decide to postpone RSV vaccination until a future visit.

People with minor illnesses, such as a cold, may be vaccinated. People who are moderately or severely ill should usually wait until they recover before getting RSV vaccine.

Your health care provider can give you more information.

#### 4. Risks of a vaccine reaction

 Pain, redness, and swelling where the shot is given, fatigue (feeling tired), fever, headache, nausea, diarrhea, and muscle or joint pain can happen after RSV vaccination.

Serious neurologic conditions, including Guillain-Barré syndrome (GBS), have been reported after RSV vaccination in clinical trials of older adults. It is unclear whether the vaccine caused these events.

Preterm birth and high blood pressure during pregnancy, including pre-eclampsia, have been reported among pregnant people who received RSV vaccine during clinical trials. It is unclear whether these events were caused by the vaccine.

People sometimes faint after medical procedures, including vaccination. Tell your provider if you feel dizzy or have vision changes or ringing in the ears.

As with any medicine, there is a very remote chance of a vaccine causing a severe allergic reaction, other serious injury, or death.

### 5. What if there is a serious problem?

An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call 9-1-1 and get the person to the nearest hospital.

For other signs that concern you, call your health care provider.

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your health care provider will usually file this report, or you can do it yourself. Visit the VAERS website at <a href="https://www.vaers.hhs.gov">www.vaers.hhs.gov</a> or call 1-800-822-7967. VAERS is only for reporting reactions, and VAERS staff members do not give medical advice.

#### 6. How can I learn more?

- · Ask your health care provider.
- · Call your local or state health department.
- Visit the website of the Food and Drug Administration (FDA) for vaccine package inserts and additional information at <a href="https://www.fda.gov/vaccines-blood-biologics/vaccines">www.fda.gov/vaccines-blood-biologics/vaccines</a>
- Contact the Centers for Disease Control and Prevention (CDC):
- Call 1-800-232-4636 (1-800-CDC-INFO) or
- Visit CDC's website at www.cdc.gov/vaccines.

To allow medical care provider(s) accurate immunization status information, an immunization assessment, and a recommended schedule for future immunizations, information will be sent to the Michigan Care Improvement Registry. Individuals have the right to request that their medical care provider not forward immunization information to the Registry.

MDHHS-Pub-1748

AUTH: P. H. S., Act 42, Sect. 2126

Vaccine Information Statement RSV Vaccine

10/19/2023







# RSV Immunization for Infants and Young Children



# RSV is the Leading Cause of Hospitalization in U.S. Infants<sup>1</sup>

- Most (68%) infants are infected in the first year of life and nearly all (97%) by age 2 years<sup>2</sup>
- 2–3% of young infants will be hospitalized for RSV<sup>3,4,5</sup>
- RSV is a common cause of lower respiratory tract infection in infants
- Highest RSV hospitalization rates occur in first months of life and risk declines with increasing age in early childhood<sup>3,5</sup>
- 79% of children hospitalized with RSV aged less than 2 years had no underlying medical conditions<sup>3</sup>

<sup>1</sup>Suh et al. JID 2022; <sup>2</sup>Glezen et al, Arch Dis Child, 1986; <sup>3</sup>Hall et al, Pediatrics, 2013; <sup>4</sup>Langley & Anderson, PIDJ, 2011; <sup>5</sup>CDC NVSN data

# RSV Prevention for Infants and Young Children

- On July 17, 2023, <u>FDA</u> approved nirsevimab (brand name Beyfortus) for the prevention of RSV disease in neonates and infants born during or entering their first RSV season and in children who remain vulnerable to severe RSV disease through their second RSV season
- On August 3rd, 2023, ACIP met and voted unanimously to approve the recommendations
  - For RSV
  - Vaccines for Children resolution
- On August 25, 2023, the CDC published an MMWR with recommendations for the use of nirsevimab for the prevention of RSV disease in infants and young children

## **ACIP** Recommendations

- Infants aged less than 8 months born during or entering their first RSV season are recommended to receive one dose:
  - Nirsevimab 50mg (0.5ml) for infants who weigh less than 5kg (11 lbs.)
     or
  - Nirsevimab 100mg (1 ml) for infants who weigh 5kg (11 lbs.) or more
- Children aged 8 months through 19 months of age who are at increased risk for severe RSV disease and entering their second RSV season are recommended to receive
  - One 200mg dose of nirsevimab (2 separate injections given at same time, 2 separates sites [1 inch apart]-100mg each)

Nirsevimab Use for RSV in Infants and Young Children: MMWR (cdc.gov)

# Recommendations For Increased Risk During Second RSV Season

- The following children aged 8 through 19 months are recommended to get a dose when entering their **second** RSV season:
  - Children with chronic lung disease of prematurity who required medical support (chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen) any time during the 6-month period before the start of the second RSV season
  - Children with severe immunocompromise
  - Children with cystic fibrosis who have either:
    - Manifestations of severe lung disease (previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest imaging that persist when stable) or
    - Weight-for-length less than 10th percentile
  - American Indian or Alaska Native children

# Timing of Nirsevimab Administration

- Optimal timing for nirsevimab administration is shortly before the RSV season begins; however, nirsevimab may be administered to age-eligible infants and children who have not yet received a dose at any time during the season. Only a single dose of nirsevimab is recommended for an RSV season
- On the basis of pre-COVID-19 patterns, nirsevimab could be administered in most of the continental U.S. from October through the end of March. However, because RSV activity might vary geographically, providers can adjust administration schedules based on local epidemiology
- Infants born shortly before or during the RSV season should receive nirsevimab within 1 week of birth
- Nirsevimab administration can occur during the birth hospitalization or in the outpatient setting

# Nirsevimab Following Maternal RSV Immunization

- Nirsevimab is recommended for infants aged less than 8 months born during or entering their first RSV season:
  - Whose mother did not receive Abrysvo OR
  - Whose mother's receipt of Abrysvo is unknown OR
  - Who were born less than 14 days after maternal vaccination
- Infants and children aged 8 through 19 months who are at increased risk for severe RSV disease and are entering their second RSV season are recommended to receive nirsevimab regardless of maternal vaccination with Abrysvo

HAN—CDC Alert and Guidance Regarding Limited Supply of Nirsevimab (RSV Monoclonal Antibody) (govdelivery.com)



# Nirsevimab Following Maternal RSV Immunization Cont.

- Nirsevimab may be considered for infants born to vaccinated mothers in rare circumstances. These situations include but are not limited to:
  - Pregnant person was immunosuppressed when receiving RSVpreF
  - Pregnant person has HIV (regardless of immunosuppression) when receiving RSVpreF
  - Child has undergone cardiopulmonary bypass surgery or extracorporeal membrane oxygenation
  - Child has hemodynamically unstable congenital heart disease
  - ICU admission requiring oxygen at hospital discharge



## **New Interim Recommendations**

- Nirsevimab use during limited availability:
  - For infants weighing less than 5kg (11 lbs.) recommendations are unchanged. For infants born during October 2023 and through the RSV season, administer a 50mg dose of nirsevimab in the first week of life
  - Infants weighing 5kg (11 lbs.) or more prioritize using 100mg
     nirsevimab doses in infants at highest risk of severe RSV disease:
    - Young infants aged less than 6 months
    - American Indian and Alaska Native infants aged less than 8 months



## New Interim Recommendations Cont.

- Infants aged 6 through 7 months with conditions that place them at high risk of severe RSV disease:
  - o Premature birth at less than 29 weeks' gestation,
  - Chronic lung disease of prematurity
  - Hemodynamically significant congenital heart disease
  - Severe immunocompromise
  - Severe cystic fibrosis with either manifestations of severe lung disease or weight-for-length less than 10<sup>th</sup> percentile
  - Neuromuscular disease
  - Congenital pulmonary abnormalities that impair the ability to clear secretions



## New Interim Recommendations Cont.

- In palivizumab-eligible children aged 8–19 months, suspend using nirsevimab for the 2023–2024 RSV season. These children should receive palivizumab per <a href="American Academy of Pediatrics">American Academy of Pediatrics</a> (AAP) recommendations
- Continue offering nirsevimab to American Indian and Alaska Native children aged 8–19 months who are not palivizumab-eligible and who live in remote regions, where transporting children with severe RSV for escalation of medical care may be challenging, or in communities with known high rates of severe RSV among older infants and toddlers
- Follow <u>AAP recommendations</u> for palivizumab-eligible infants aged <8 months when the appropriate dose of nirsevimab is not available



## New Interim Recommendations Cont.

 Avoid using two 50mg doses for infants weighing 5 kg (11 lbs) or more to preserve supply of 50mg doses for infants weighing less than 5 kg (less than 11 lbs)

### Reminder:

Providers should encourage pregnant people to receive RSVpreF vaccine (Abrysvo, Pfizer) during 32 weeks through 36 weeks gestation to prevent RSV-associated lower respiratory tract disease in infants.
 Only the Pfizer RSVpreF vaccine (Abrysvo) is approved and recommended for use in pregnant people. The GSK RSVpreF3 vaccine (Arexvy) should **not** be used in pregnant people

## Respiratory Syncytial Virus (RSV)-Nirsevimab

Nirsevimab 50mg (50mg/0.5mL) pre-filled syringe Nirsevimab 100mg (100mg/mL) pre-filled syringe with a purple plunger rod with a light blue plunger rod Miles and the second se **Beufortus Beyfortus** pre the pre-filled syringe in original carton to protect from light until time of use. amuscular Injection Only re-filled syringe in original carton to protect from light until time of use Recommended dosage of nirsevimab in infants less than 8 months of age born during or entering their first RSV season: Weigh Less Than 5kg (11lb) Weigh 5kg (11lb) or More 50mg (purple plunger) 100mg (light blue plunger) Recommended dosage of nirsevimab for infants 8 through 19 months who are at increased risk for severe RSV disease and entering their second RSV season: 200mg (administered as two 100mg [light blue plunger] injections given at the same time at different injection sites)

## Nirsevimab: Storage and Handling and Administration

- Store refrigerated between 36°F to 46°F (2°C to 8°C)
- May be kept at room temperature 68°F to 77°F (20°C to 25°C) for a maximum of 8 hours
- After removal from the refrigerator, nirsevimab must be used within 8 hours or discarded
- Store in original carton to protect from light until time of use
- Do not freeze, shake, or expose to heat
- Sterile, preservative-free, clear to opalescent, colorless to yellow solution
- Intramuscular injection only
- In accordance with general best practices for immunization, simultaneous administration of nirsevimab with age-appropriate vaccines is recommended

#### Talk with your health ca

Tell your health care provider

- · History of serious allergic re
- Bleeding disorder, or
- Moderate or severe acute il

In some cases, your child's he future visit.

People who have a minor illne moderately or severely ill sho

Your health care provider can

#### Risks of a reaction to R

After getting an RSV preventi injection was given, or a rash

As with any medicine, there i other serious injury, or death

An allergic reaction could occ reaction (for example, hives, weakness), call 9-1-1 and get

Call your health care provide

#### What if there is a serior

If your child got an RSV prever vaccine at the same time, and you or your health care provid https://www.fda.gov/medwat

If your child got an RSV preventhe same time and you suspenhealth care provider should revent Reporting System (VAEF 1-800-822-7967. In your report Immunization along with a variation and the same statement of the same s

Note: MedWatch and VAERS MedWatch and VAERS staff m

To allow medical care provider(s) schedule for future immunization right to request that their medical

Immunization Information Statem Respiratory Syncytial Virus (RSV) I 9/25/2023

#### **IMMUNIZATION INFORMATION STATEMENT**

### Respiratory Syncytial Virus (RSV) Preventive Antibody:

What You Need to Know

#### Why get immunized with a RSV preventive antibody?

A respiratory syncytial virus (RSV) preventive antibody can prevent severe lung disease caused by RSV.

RSV is a common respiratory virus that usually causes mild, cold-like symptoms but can also affect the lungs. Symptoms of RSV infection may include runny nose, decrease in appetite, coughing, sneezing, fever, or wheez

Anyone can become infected by RSV, and almost all children get an RSV infection by the time they are 2 years of While most children recover from an RSV infection in a week or two, RSV infection can be dangerous for infants and some young children, causing difficulty breathing, low oxygen levels, and dehydration. In the United States RSV is the most common cause of bronchiolitis (inflammation of the small airways in the lungs) and pneumonic (infection of the lungs) in children younger than 1 year of age. Children who get sick from RSV may need to be hospitalized, and some might even die.

#### **RSV Preventive Antibodies**

The RSV preventive antibody (generic name nirsevimab, trade name Beyfortus) is a shot that prevents severe I disease in infants and young children. Antibodies are proteins that the body's immune system uses to fight off harmful germs. Like traditional vaccines, preventive antibodies are immunizations that provide protection agai a specific pathogen. While both are immunizations, the way they provide immunity is different. Nirsevimab is an immunization that provides antibodies directly to the recipient. Traditional vaccines are immunizations that stimulate the recipient's immune system to produce antibodies.

Infants born during the RSV season (typically fall through spring) should receive a single dose of the RSV Immunization within 1 week after birth. Most infants whose mothers got the RSV vaccine don't need to get nirsevimab, too. Both protect infants from severe RSV by providing antibodies, either from the mother to the infant or directly to the infant. Most infants will likely only need protection from either the maternal RSV vaccinirsevimab (not both). However, there may be some situations in which nirsevimab would be recommended for infant after the mother received an RSV vaccine.

Infants born outside of the RSV season who are younger than 8 months should receive a single dose of the RSV Immunization shortly before their first RSV season (typically the fall), but infants who are younger than 8 mont who have not yet received a dose may receive a dose at any time during the season.

Some infants and young children who are at increased risk for severe RSV disease may need a single dose of th RSV antibody before or during their second RSV season.

RSV preventive antibodies can be given at the same time as vaccines routinely recommended for infants and young children.



### **Monoclonal Antibody Fact Sheet**

### Differences between vaccines and monoclonal antibodies

	Vaccine	Monoclonal Antibody
Type of immunity	Active	Passive
How it works	Stimulates the immune system to produce antibodies that provide protection against disease	A molecule that mimics an antibody which will help provide protection against disease
How long it takes to be effective	Typically 10 days to 2 weeks following vaccination	Almost immediately after administration
How long protection lasts	Usually provides long-term protection	Usually provides short-term protection (months)

Types of Immunity to a Disease | CDC

Immunization Information Statement (IIS)

#### Clinical Considerations for Use of Maternal RSV Vaccine or Infant RSV Monoclonal Antibody

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#### **Product**

(Administration Sho Typically Be Deferre Safety

Precautions

\$Children 8-19 months who are at children; children who are severe children with chronic lung disease start of their second RSV season) 100 mg light blue plunger rod) sh

\$One dose for each RSV season where an additional dose is reco Clinical Considerations for Use of Maternal RSV Vaccine or Infant RSV Monoclonal Antibody

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#### Product Description

Immunity

#### **Duration of Protecti**

How Supplied

Recommended Dosage

Number of Doses **How Administered** Coadministration

Gestation or Age for **Immunization** 

When to Administe (Seasonality)

Contraindications (Product Should No Be Administered)

Respiratory Syncytial Virus vaccines (RSV) **Options for Infant RSV Prevention** At-a-Glance

Two immunization products are available for the prevention of severe Respiratory Syncytial Virus (RSV) disease in infants: maternal RSV vaccine and infant RSV monoclonal antibody. All infants should be protected against severe RSV disease through use of one of these products.

Either maternal RSV vaccination or use of RSV monoclonal antibody in the infant is recommended. Administration of both products is not needed for most infants.

Maternal RSV vaccination: Use ONLY Pfizer RSVPreF vaccine (trade name Abrysvo™)

#### Maternal RSV Vaccine

RSVPreF vaccine (trade name Abrysvo™) is recommended for people during weeks 32 through 36 of pregnancy, using seasonal administration, to prevent severe RSV disease in infants. In clinical trials, there was a small increase in the number of preterm birth events in vaccinated pregnant people after vaccination. It is not clear if this is a true safety problem related to RSV vaccine or if this occurred for reasons unrelated to vaccination.

#### Infant RSV Monoclonal Antibody\*

RSV monoclonal antibody (generic name nirsevimab, trade name Beyfortus™) is recommended for the following:

- . Infants less than 8 months of age born during or entering their first RSV season if:
  - Mother did not receive maternal RSV vaccine or it is unknown if mother received RSV vaccine
  - Infant was born less than 14 days after maternal RSV vaccination

In rare circumstances, nirsevimab may be considered for infants born to mothers vaccinated 14 or more days before birth when the health care provider believes the potential incremental benefit is warranted. These situations include, but are

- Infants born to mothers who might not have mounted an adequate immune response to vaccination (e.g., people with immunocompromising conditions)
- Infants born to mothers who have conditions associated with reduced transplacental antibody transfer (e.g., people living
- Infants who might have experienced loss of maternal antibodies, such as those who have undergone cardiopulmonary bypass of extracorporeal membrane oxygenation (ECMO)
- Infants with substantial increased risk for severe RSV disease (e.g., hemodynamically significant congenital heart disease, intensive care admission with the requirement for oxygen at hospital discharge)
- . Some infants and children aged 8 through 19 months who are at increased risk of severe RSV disease entering their second RSV season.
  - American Indian/Alaska Native children
  - Children with chronic lung disease of prematurity who require medical support during the six months before the start of their second RSV season
  - Children with severe immunocompromise
  - Children with severe cystic fibrosis

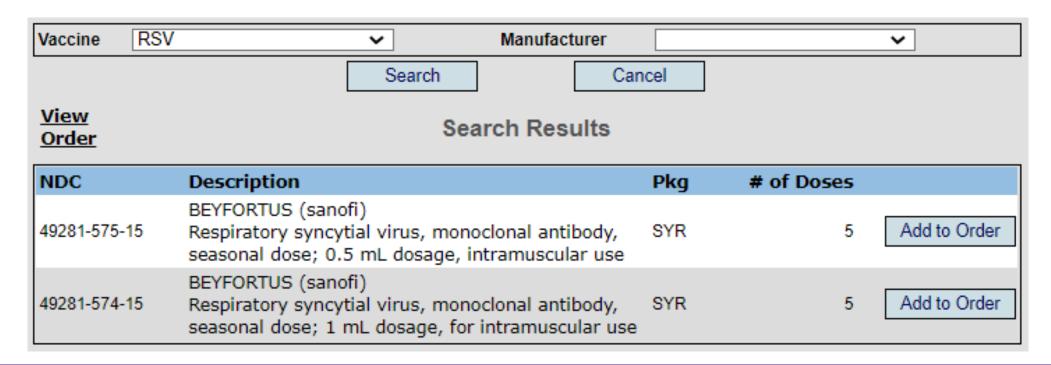
RSV disease. Please see <u>AAP guidelines for pally/zumab</u>. AAP has published considerations on the use of nirsevimab and pally/zumab: <a href="https://pre/redbook/resources/25378">https://pre/redbook/resources/25378</a>. Children who have received nirsevimab should not receive pally/zumab during the same RSV season.

From time of maternal vaccination, at least 14 days are needed for the development and transplacental transfer of maternal antibodies to protect the infant

At-a-Glance on Options for Prevention of RSV Disease in **Infants** 

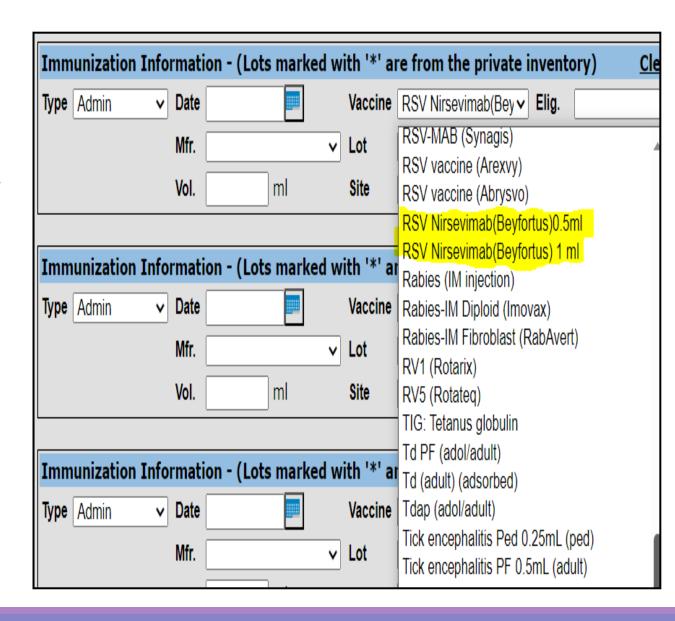
### Nirsevimab and MCIR

- Ordering VFC nirsevimab in MCIR:
  - Order as you do other VFC vaccines through MCIR e-ordering



## Nirsevimab and MCIR Cont.

- Documenting administration of 2.0 mL nirsevimab in MCIR:
  - MCIR deduplication rules have been enhanced to support administration of two (2) CVX 307 (Beyfortus 1.0 mL) to the same child on the same day
  - Rules: Subsequent vaccination (the split dose) must have the following:
    - Same vaccine manufacturer (product) for CVX 307
    - Same reporting facility
    - Same admin date
    - Same dose volume
    - Sum of dose volumes must be 2.0 mL





## Reporting of Adverse Reactions:

- Adverse reactions that occur after administration of nirsevimab alone may be reported to MedWatch online (<a href="https://www.fda.gov/medwatch">https://www.fda.gov/medwatch</a>), by fax, by mail, or by contacting FDA at 1-800-FDA-1088
- Adverse reactions that occur after coadministration of nirsevimab with another vaccine should be reported to the Vaccine Adverse Event Reporting System (VAERS), and reports should specify that the patient received nirsevimab on the VAERS form. Reports can be submitted to VAERS online (<a href="https://vaers.hhs.gov">https://vaers.hhs.gov</a>), by fax, or by mail. When adverse reactions that occur after the coadministration of nirsevimab with a vaccine are reported to VAERS, additional reporting of the same adverse reactions to MedWatch is not necessary



# Recent Ordering Updates

- MDHHS was supplied with a very limited allocation of Nirsevimab 50 mg and 100 mg doses.
- Orders will be prioritized by the following:
  - 1. Tribal Health Centers
  - 2. Health System (birthing centers)
  - 3. Local Health Departments
  - 4. Federally Qualified Health Centers (FQHCs)
  - 5. Migrant Health Centers
  - 6. Private VFC Providers
- Orders for nirsevimab may be placed and those orders will be monitored to ensure equitable access of our limited supply.
- The minimum order quantity for both the 50 mg and 100 mg supply of nirsevimab is
   5 doses and the maximum order quantity will be 10 doses at this time.

## Nirsevimab Addendum: Inventory



### **Nirsevimab Addendum: Inventory**

- All VFC providers will be allowed a flexible, time-limited ramp-up period to meet the private inventory requirement for nirsevimab; during this time awardees will not require VFC providers to meet the private inventory requirements for nirsevimab if they do not intent to vaccinate their private pay patients. VFC providers are required to meet the private inventory requirement no later than August 1, 2024.
- If VFC providers utilize this flexibility to not provide private stock during this season, providers should explore if other in-network options exist for their private patients to access nirsevimab (i.e., from another local in-network practice or system who does have private inventory of nirsevimab, or FQHC, RHC, or deputized VFC provider authorized to immunize underinsured children).



## Nirsevimab Addendum: Inventory

- In locations where providers report that demand for nirsevimab vaccine is low, awardees are to allow providers to order the minimum packaging of vaccine feasible.
- At the discretion of the awardee, certain specialty providers, including birthing facilities (e.g., birthing hospitals or centers), may offer a limited formulary of vaccines, based on the populations served in their facility. VFC-enrolled birthing facilities offering nirsevimab must offer hepatitis B vaccine at birth as well (and vice versa).

### Nirsevimab Addendum

#### **Resources:**

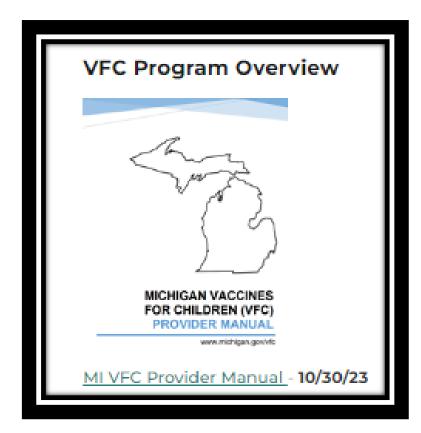
CDC VFC webpage
VFC Nirsevimab addendum
Health Alert Network (HAN) Interim CDC Recommendations

- The CDC and Health Alert network (HAN) guidance is focused toward making sure VFC eligible children are the *first obligation* for receiving Nirsevimab.
- Although the 2023-2024 VFC Operations Guide and the recently released addendum reiterated previous and long-standing policy for bidirectional borrowing, due to limited allocations MDHHS will not allow bi-directional borrowing between inventory stock.

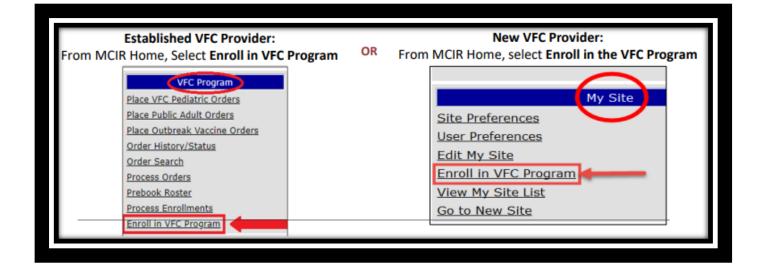
## Nirsevimab Addendum: Eligibility

### Eligibility:

- Providers will screen children the same as they would for any other VFC vaccines.
- If a birthing hospital/center is interested in carrying nirsevimab then they will need to initiate the VFC enrollment on their home screen in MCIR.
  - If a birthing hospital determines that they will provide nirsevimab the expectation, per CDC, is that the provider must also offer hep B vaccine through the Universal Hepatitis B program.
- Once enrollment within MCIR has been completed the health system will need to work closely with their LHD to ensure VFC requirements are being followed.
- Any request for specialty provider status needs prior approval by the MDHHS VFC team, please email Kyle at <u>wildtk@michigan.gov</u>, Darcy <u>wildtd@michigan.gov</u> and Heather <u>barnesh2@michigan.gov</u>



**Resource Manual** 



MCIR Screen For Enrolling Into The VFC Program



# Thank you for everything you do!

NEXT "NOONTIME KNOWLEDGE": TBD

Stay up-to-date by joining the MDHHS Listserv

 To sign up, email Dara Barrera at: <u>djbarrera@msms.org</u> and request to be added to the MDHHS Immunization Listsery

Questions? Please email:

checcimms@michigan.gov